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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,177	11/13/2003	Ronald E. Stickney	009.4001	9819

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EXAMINER	
SMITH, STEPHANIE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,177	STICKNEY ET AL.	
	Examiner	Art Unit	
	Stephanie Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *13 November 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on November 13, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 24, and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (U.S. 53191187). With reference to claims 1, 24, 30, and 31, Freeman teaches that an external defibrillator with electrodes to sense electrocardiographs and deliver shocks or pacing pulses (see figure 2 and column 2, lines 34-49). The device also contains an ECG processor that determines whether a waveform is shockable and whether the stimulus delivered is a defibrillation shock or a pacing stimulus (see column 3, lines 53-54 and column 4, lines 9-22 and figure 5). The device also contains a central processing unit that controls the pacing circuit and defibrillation (see column 3, lines 11-21). While not stated explicitly that the controller determines a magnitude and rate at which to provide pacing, it is well known in the art

that different forms of arrhythmias are treated with different levels of voltages at different rates. With reference to claims 2 and 3, Freeman teaches that the device detects bradycardia and asystole (see column 1, lines 65-67). Referring to claims 27-29, Freeman teaches that a patient can be suffering from cardiac arrest that is treated with a defibrillation shock. After the shock, if bradycardia is detected, the patient can be treated with pacing (see column 4, lines 22-25). The device also informs the user that delivery of a shock is needed if the shock advisory algorithm detects that a shock is needed (see column 4, lines 28-30). Further, the device contains control knobs and buttons (see figure 1 and column 2, lines 50-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman. Freeman discloses the claimed invention but does not disclose expressly comparing the physical parameters sensed to predetermined parameters indicating second or third degree atrioventricular block. It would have been an obvious matter of design choice to a person of ordinary skill I the art to modify the defibrillator and method taught by Freeman with second and third degree atrioventricular parameters, because Applicant has not disclosed that the second and third degree atrioventricular parameters provide an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the QRS complex parameters as taught Freeman, because it provides an indication as to what type of arrhythmia is occurring and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Freeman. Therefore, it would have been an obvious matter of design choice to modify Freeman to obtain the invention as specified in claims 4 and 5.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Kroll et al (U.S. 6167306). Freeman teaches the device and method described above, but does not teach detecting for low cardiac output. Kroll et al. teach detecting the presence of low cardiac output (see claim 39). Low cardiac output could be indicative of a block within the heart and would indicate that the patient needs stimulation in order to allow the heart to beat at a normal pace. Therefore, it would have

been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillation and pacing taught by Freeman with the monitoring for low cardiac output taught by Kroll et al. in order to determine if the patient needs stimulation therapy.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Taylor et al (U.S. 6304773). Freeman teaches the defibrillating and pacing as described above, but does not teach determining that a shock has been delivered within a predetermined period of time. Taylor et al. teach determining that a shock has been delivered within a predetermined period of time (see column 16, lines 24-27). Determining that a shock has been delivered within a period of time would prevent the user of the defibrillator from delivering shocks within a period of time such that it could cause damage to the heart. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the determination that a shock has been delivered within a predetermined time in order to prevent a second shock from being delivered and damaging the heart.

6. Claims 8-17, 20, 23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Snyder et al (U.S. 6356785). Regarding claim 8, Freeman teaches the defibrillating and pacing as described above, but does not teach obtaining and analyzing updated physical parameters. Snyder et al. does teach obtaining and analyzing updated parameters (see figures 16B and 17B). Continual monitoring of parameters would allow the user of the defibrillator to provide the correct

therapy for the current status of the patient. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the monitoring of updated parameters in order to provide the correct therapy for the current status of the patient.

7. With regards to claims 9 and 25, Freeman teaches the defibrillating and pacing as described above, but does not teach adjusting the pacing therapy based upon the current status of the patient. Snyder et al. does teach adjusting the pacing therapy based upon the current status of the patient (see column 25, lines 26-34). It is well known in the art that a patient's condition may change during treatment, and that different therapies may be needed to treat different conditions. If the same therapy is continued to be used even though the condition of the patient has changed, the patient's condition may worsen instead of improve. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the updating of the therapy in order to ensure that the patient's condition improve instead of worsen.

8. Referring to claims 10 and 26, Freeman teaches the defibrillating and pacing as described above, but does not teach terminating therapy based upon the updated physical parameters. Snyder et al. do teach terminating therapy based upon the updated physical parameters if the parameters indicate normal cardiac rhythm (see column 21, lines 36-39 and column 17, lines 10-18). Terminating the therapy once normal cardiac rhythm has been determined would be beneficial to the patient in order to prevent inducing an arrhythmia. Therefore, it would have been obvious to one skilled

in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the early termination of therapy once normal cardiac rhythm has been detected in order to prevent inducing an arrhythmia.

9. With reference to claims 15 and 17, Freeman teaches the defibrillating and pacing as described above, but does not teach determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment. Snyder et al. teaches determining if the heart condition would be appropriately treated with non-electrotherapeutic treatment (see figure 4 and column 9, lines 63-67 and column 10, lines 1-6). Not all abnormal heart rhythms can be best treated by defibrillation, and therefore, attempting to treat them with defibrillation can cause damage to the heart. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the non-electrotherapeutic treatment in order to prevent causing damage to the heart.

10. With regards to claims 16 and 23, Freeman teaches the defibrillating and pacing as described above, but does not teach indicating the physical status of the patient to the user. Snyder et al. do teach indicating the physical status of the patient to the user (see column 10, lines 3-6 and column 6, lines 42-51). Alerting the user to the physical status of the user allows the user to deliver the proper therapy to the patient. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the indicating the physical status of the patient to the user so that the user can deliver the proper therapy to the patient.

11. Referring to claim 20, Freeman teaches the defibrillating and pacing as described above, but does not teach monitoring the patient's blood oxygen levels. Snyder et al. do teach monitoring the patient's blood oxygen levels (see figure 15). Blood oxygen levels indicate how much oxygen is being transported in the blood and is an indirect indication of how well the heart is pumping. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the defibrillating and pacing taught by Freeman with the monitoring of the patient's blood oxygen levels in order to determine how well the heart is pumping.

12. Regarding claims 11-14, Freeman in view of Snyder et al. disclose the claimed invention but does not disclose expressly indications to cease pacing that include identify no electrical capture, no mechanical capture, failure in improvement of cardiac output, and adequate spontaneous circulation. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the defibrillator and method taught by Freeman in view of Snyder et al. with indications to cease pacing that include identify no electrical capture, no mechanical capture, failure in improvement of cardiac output, and adequate spontaneous circulation, because Applicant has not disclosed that the indications to cease pacing that include identify no electrical capture, no mechanical capture, failure in improvement of cardiac output, and adequate spontaneous circulation provide an advantage, is used for a particular purpose, or solves a state problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the indication to cease pacing because the heart has been captured as taught Freeman in view of Snyder et al,

because it prevents the heart from experiencing further damage due to electrical stimulation and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Freeman in view of Snyder et al. Therefore, it would have been an obvious matter of design choice to modify Freeman in view of Snyder et al. to obtain the invention as specified in claims 11-14.

13. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Snyder et al. as applied to claims 10 and 16 above, and further in view of Brown et al (U.S. 5683424). With reference to claims 18 and 19, Freeman in view of Snyder et al. teach the device and method described above, but do not teach identifying spontaneous circulation. Brown et al. teaches that certain non-counter shock therapies for treating cardiac arrest may be utilized such as drug therapy and ventilation/oxygenation if certain factors of the cardiac signal fall below predetermined thresholds (see column 4, lines 63-67 and column 5, lines 1-3). Drug therapy may provide chemicals needed to adjust the speed with which the heart is beating, and ventilation may provide oxygen levels to the patient that resuscitation could not provide. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the system and method taught by Freeman in view of Snyder et al. with the ventilation and drug therapy taught by Brown et al. in order to provide increased levels of oxygen to the patient and to adjust the speed with which the heart is beating.

14. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Snyder et al. as applied to claims 10 and 16 above, and further

in view of Sherman et al (U.S. 2001/0018562). Freeman in view of Snyder et al. teach the device and method described above, but do not teach monitoring blood pressure or end tidal carbon dioxide for non-electrotherapeutic treatment. Sherman et al. do teach monitoring these parameters for non-electrotherapeutic treatment (see page 4, paragraph 27). Blood pressure is an indication of heart rate, and end tidal carbon dioxide is an indication of how well the heart is circulating blood. Therefore, it would have been obvious to one skilled in the art at the time the invention was disclosed to combine the system and method taught by Freeman in view of Snyder et al. with the monitoring of end tidal carbon dioxide and blood pressure in order to measure heart rate.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. 2003/0144699 to Freeman discloses a system and method that uses parameters such as end tidal carbon dioxide in order to determine if further resuscitation will be successful.

U.S. 5405362 to Kramer et al. disclose an external defibrillator that measures blood pressure, identifies various types of arrhythmias, and delivers appropriate electrical and drug therapy based on the type of arrhythmia occurring.

U.S. 2004/0039419 to Stickney et al. disclose a pulse detector that monitors spontaneous circulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephanie Smith 3/3/2006
SRS

GEORGE R. EVANISKO
PRIMARY EXAMINER
3/3/6